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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,287	02/19/2004	Jei-Fu Shaw	70002-104001	4293

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OCCHIUTI ROHLICEK & TSAO, LLP
10 FAWCETT STREET
CAMBRIDGE, MA 02138

EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
01/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Office Action Summary	Application No.	Applicant(s)	
	10/782,287	SHAW ET AL.	
	Examiner	Art Unit	
	TAEYOON KIM	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-16,18-20,31-36 and 45-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-16,18-20,31-36 and 45-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/15/2008 has been entered.

Response to Amendment

Applicant's amendment and response filed on 9/15/2008 and supplemental amendment filed on 10/30/2008 have been received and entered into the case.

Claims 1-13, 17, 21-30 and 37-44 are canceled, claims 45-52 are newly added, and claims 14-16, 18-20, 31-36 and 45-52 are pending and have been considered on the merits. All arguments have been fully considered.

The claim rejection under 35 U.S.C.§112, 1st para., in the previous office action has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C.§103 based on Seidman et al. in view of Iwano et al. has been withdrawn due to the amendment. However, the claim rejection under 35 U.S.C.§103 based on Seidman et al. in view of Skory et al. is maintained (see below).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16, 18-20, 31-36 and 45-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the condition where the glucose concentration being 105 mg/ml for the fermentation process, does not reasonably provide enablement for the glucose concentration less than the above concentration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The claims are drawn to methods of producing ethanol by saccharification of starch using two different enzymes forming glucose-rich syrup, followed by fermentation of the syrup with Aspergillus oryzae.

The limitations of the claims are too broad to encompass any concentration of glucose-rich syrup, and any strain of Aspergillus oryzae. The claims indicate that with

any concentration of glucose-rich syrup obtained by consecutive saccharification with two enzymes (a-amylase and glucoamylase), the method would result in the production of ethanol at 10.5% by 3 days or 13.5% by 5 days.

However, the limitation of 10.5% or 13.5% ethanol concentration disclosed in the claims is derived from the example disclosed in the specification, where only a specific glucose concentration allows the claimed yield by the fermentation process, but not with other concentration of glucose. The specification clearly indicated that, the yield of ethanol for glucose at 11 mg/ml is only 1%. Whereas with the glucose concentration at 105 mg/ml, which is 10 fold more, the yield of ethanol reaches 10.5% by 3 days and 13.5% by 5 days under the same fermentation condition (p.7, example 4). Therefore, the claimed yield of ethanol at 10.5% or 13.5% cannot be achieved by the glucose concentration less than 105 mg/ml even if the same fermentation condition is used for the process.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-16, 18-20, 31-36 and 45-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidman et al. (of the record) in view of Skory et al. (of the record).

Seidman et al. teach a process of liquefying starch derived from rice, tapioca,

sorghum, potatoes, etc. (see column 5, lines 6-10) to a soluble hydrolysate using α-amylase at a temperature about 170°F-195°F, which is 76.7°C-90.5°C (see column 2, lines 46-60), and then a saccharification enzyme such as glucoamylase in the second step (see column 2, lines 8-12).

Seidman et al. teach that the saccharification product is dextrose-rich solution (col. 3, lines 55-60), and it is well known in the art that dextrose is a synonym of glucose, and thus, the dextrose-rich solution of Seidman et al. is considered as glucose-rich syrup.

Seidman et al. do not teach the step for producing ethanol by fermentation with Aspergillus oryzae for 3 or 5 days.

Skory et al. teach a fermentation process of simple sugars (glucose) using Aspergillus oryzae to produce ethanol (fermentation product) (see Table 1), and Skory et al. also show various duration of fermentation including 3-5 days and the yield of ethanol (see Fig.1).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try to use Aspergillus oryzae to ferment the glucose-rich syrup of Seidman et al. to produce fermentation product because it is well known in the art that Aspergillus oryzae is one of commonly used fungi in fermentation.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007) “The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was “obvious to try.” Id., at 289 (internal quotation marks omitted). When there

is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103." See also M.P.E.P. §2141.

Furthermore, it is well known in the art that saccharification and fermentation can be carried out simultaneously (also known as simultaneous saccharification fermentation; SSF), and Skory et al. also teach SSF for the production of ethanol using Aspergillus oryzae (p.203, left col.). Since Seidman et al. utilize enzymes from Aspergillus oryzae (col. 5, lines 62-66) for saccharification, and the same microorganism can be used for fermentation of ethanol as taught by Skory et al., it would have been obvious to a person of ordinary skill in the art to use Aspergillus oryzae for saccharification as well as fermentation of ethanol using dextrose-rich solution of Seidman et al. in view of Skory et al.

With regard to the yield of ethanol being 10.5% or 13.5%, Seidman et al. in view of Skory et al. do not particularly teach the concentration. However, since it is well known in the art that the yield of ethanol from fermentation is variable based on the several parameters including amount of substrate (e.g. glucose), microorganism strains, duration of fermentation, etc., an artisan of ordinary skill in the art would have recognized that the yield of ethanol by using the method of Seidman et al. in view of Skory et al. would be routinely optimized.

Furthermore it is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re* Aller, Lacey, and Haft, 105 USPQ 233 (CCPA 1955): Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. *In re* Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931,24 USPQ 52; *In re* Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. *In re* Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; *In re* Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. *In re* Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re* Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; *In re* Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re* Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11,57 USPQ 136. (Emphasis added). With regards

to determining experimental parameters, such as time in culture, the court has held that "[d]iscovery of optimum value of result effective variable in known process is ordinarily within skill of art (In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980)).

Still further, the limitation of ethanol concentration having 10.5% or 13.5% is result from the method claimed in the current application. The limitation does not require any process step to be carried out other than disclosed in the current claims. Thus, the limitation does not limit the method of the current invention. Since the method steps of Seidman et al. in view of Skory et al. is substantially similar, if not identical, the results obtainable from the methods of Seidman et al. in view of Skory et al. is expected to be the same as the claimed invention.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Applicant argued that the percentage of ethanol produced in a 6-day fermentation period according to Skory et al. is 1.59-2.44%, which is far less than the claimed percentage of 10.5% or 13.5%. The argument is fully considered but not persuasive because applicant's argument is against the individual references, rather then the references in combination, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The teaching of Skory et al. combined with the teaching of Seidman et al. is the

use of A. oryzae for the ethanol Fermentation process using the glucose-rich solution of Seidman et al. Although Skory et al. disclose the yield of ethanol, it is not based on the method of Seidman et al. Seidman et al. teach a method to produce glucose-rich solution or syrup as the claimed in the current invention. While Skory et al. disclose the use of glucose as a substrate for the fermentation process, the pure glucose used in the method of Skory et al. is different from the glucose-rich solution of Seidman et al. in their concentration. Like the glucose-rich syrup claimed in the instant application, the dextrose-rich solution of Seidman et al. is not purely glucose solution. It contains other partially hydrolyzed polysaccharides along with dextrose/glucose. Therefore, even if the yield of Skory et al. is compared to the ethanol yield of the current invention, there is significant difference in the concentration of carbon sources utilized for fermentation between the method of Skory et al. and the claimed method.

Furthermore, as Skory et al. discloses, the yield of ethanol from 50 g/l of glucose by fermenting with A. oryzae NRRL 694 is nearly 100% of theoretical yield (p.204, Results and discussion). Considering the ethanol yield of the current claim being at best 100% or less of the theoretical yield, the strain of Skory et al. is capable of producing the comparable amount of ethanol under the same condition as the claimed invention. Since the method steps and materials used in the method of Seidman et al. in view of Skory et al. is substantially similar, if not identical, and A. oryzae strain of Skory et al. is capable of nearly 100% of theoretical yield, a person of ordinary skill in the art would have expected that the method of Seidman et al. in view of Skory et al. is capable to produce the substantially similar, if not identical, yields in ethanol/wine production.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Examiner, Art Unit 1651